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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/665,973	Applicant(s) TRAN ET AL.	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-35,37-44 and 55-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-35,37-44 and 55-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed on October 2, 2009. Examiner acknowledges claims 28-35, 37-44, and 55-58 are pending in this application, with claim 28 having been currently amended and claims 1-27, 36, and 45-54 having been cancelled.

Drawings

2. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “the whole of the coil disposed nearer the distal end” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 28-35, 37-44, and 55-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP § 608.04.

Specifically, claim 28 now recites the claim limitation "the whole of the coil disposed nearer the distal end of the catheter body"; however, the originally filed disclosure does not provide evidence that Applicant possessed the newly claimed invention at the time the application was filed. In fact, the original disclosure of the instant invention, as seen in Figure 4, discloses a coil (48) extending through both the

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distal and proximal ends of the catheter body, which is different from the claimed "whole of the coil disposed nearer the distal end of the catheter body". Applicant is reminded that "any negative limitation or exclusionary proviso must have basis in the original disclosure. MPEP § 2173.05(i). There is no specific recitation or support for "the whole of the coil disposed nearer the distal end of the catheter body" in the original disclosure as filed; and therefore, the subject matter added to the claim 28 and its dependents, claims 29-35, 37-44, and 55-58, is considered new matter and must be cancelled from the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977); *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F. 2d 453 (Fed. Cir. 1984); and *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Claim Rejections - 35 USC § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 28-35, 37-44, and 55-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP § 608.04.

Specifically, claim 28 now recites the claim limitation "at least one coil disposed along the catheter body and encircling the lumen, wherein the whole of the coil disposed nearer the distal end of the catheter body than the proximal end of the

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catheter body and extends along the distal portion and the proximal portion". From this recitation of the claim language, Examiner is unsure how a coil can both extend "along the distal and proximal portions" of a catheter, while also have "the whole of the coil extending nearer the distal end". The use of the word "whole" implies 100%; yet, by the recitation of the additional claim limitations if the "whole" or 100% of the coil is located in the distal end, then there would be no amount of the coil left to extend through the proximal end. Appropriate correction and clarification is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 28-35, 37-44, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198).

As to Claim 28, Saadat disclose a system for delivering a contraceptive device (50) within a fallopian tube (Figure 2), the system comprising: a catheter (100) comprising a lumen (110), a distal portion (107) and a proximal portion (101), a contraceptive device (50) releasably disposed at least partially within the lumen (110) of the catheter (100) near the distal portion (107); and a deployment member (120) in detachable engagement with the contraception device (50) for deploying the contraceptive device (50) from the catheter (100) (Figure 11, Figure 13, and Column 10,

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Lines 30-31). Yet, Saadat does not teach the particulars of the catheter having a coil disposed along the catheter body and extending along the distal and proximal portions, nor the varying degrees of flexibility. Berhow teaches a medical catheter (10) having a coil (16) which extends along the length of the catheter from the distal end (13) to the proximal end (12) where along the catheter (10) the flexibility of the changes for the purpose of having a reinforced catheter with resistance to kinking that may result in trauma to the patient (Figures 1-4A, Paragraphs 0061 and 0071). Therefore, it would have been obvious to one having ordinary skill in the art to modify the catheter of Saadat to include a coil having varying degrees of flexibility along the length of the catheter as taught by Berhow to provide a reinforced catheter having additional safety features to prevent patient trauma as a result of kinking.

As to Claims 29, 37, 38, 56 Berhow teaches the medical catheter is most flexible (or least hard) at the distal end and increasingly becomes less flexible (or more hard) towards the proximal end (12). (Paragraph 0061).

As to Claim 30, Berhow teaches the catheter (10) is made from multiple layers in the distal portion (13) and having a coil (16) in one of the layers. (Figures 1-3 and Paragraphs 0038 and 0051).

As to Claims 31-35 and 39-42, Berhow teaches the multiple layers comprise: an inner layer (14, polytetrafluoroethylene), a middle layer (16, stainless steel coil) and an outer layer (17, polyurethane). (Figures 1-3 and Paragraphs 0019, 0021, 0024, 0038, and 0051).

As to Claims 43, 44, and 58, Berhow teaches the use of a radiopaque marker (19) or tracer ring on the catheter (10) to permit visualization of the catheter within the patient. (Paragraphs 0058 and 0059).

As to Claim 57, Berhow teaches a tapered region (32) and a lumen (15) that extends throughout the catheter (10). (Paragraph 0038).

10. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (5,935,137) in view of Berhow et al. (2003/0135198), as applied to claim 28, and further in view of Shepherd (3,566,874).

As to Claim 55, the system of Saadat / Berhow teaches a reinforced medical catheter for delivering a contraceptive device, yet does not expressly disclose the use of a hydrophilic coating over the distal portion of the catheter. Shepherd teaches the use a hydrophilic coating over the distal end of the catheter for the purpose of reducing the irritation and infection associated with the normal use of catheters. (Abstract). Therefore, it would have been obvious to one having ordinary skill in the art to modify the system of Saadat/Berhow to include a hydrophilic coating over the catheter as taught by Shepherd for the purpose of preventing infection.

Response to Arguments

11. Applicant's arguments filed October 2, 2009 have been fully considered but they are not persuasive. Applicant asserts the combination of the prior art made of record does not disclose or teach "at least one coil disposed along the catheter body and

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encircling the lumen, wherein the whole of the coil disposed nearer the distal end of the catheter body than the proximal end of the catheter body and extends along the distal portion and the proximal portion". Examiner respectfully disagrees with Applicant's assertions.

The rejection of the prior art is based upon the combination of Saadat et al. in view of and Berhow et al. where Saadat teaches the contraceptive device, yet lacks the teaching of a coil. Berhow teaches a coil (16) within the lumen of the catheter (10) for reinforcing the catheter to prevent kinking. (Paragraph 0046). Regarding, Applicant's newly recited claim limitation of " the whole of the coil disposed nearer the distal end of the catheter body" is supported by the embodiment as described in paragraph 0051 of Berhow et al. In this embodiment, Berhow teaches the coil (16) is terminated proximal to the distal end of the catheter to enable a kink resistant and flexible distal tip (13) of the catheter (10). In essence, as this recitation supports the placement of the coil in the distal tip prior to the proximal portion of the catheter to provide a different kink resistance and flexibility between the portions of the catheter having the coil and the portions of the catheter not having the coil, this newly recited feature is supported by the combination of the prior art.

Therefore, in light of the aforementioned reasoning the rejection of the claims has been maintained and made final.

Conclusion

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

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